REMARKS

Claims 1-26 are currently pending, with claims 1, 14-16, 18, 20-23 and 26 having been amended through this paper. Applicants respectfully request favorable consideration of the present application in light of the amendments to the claims and the following remarks.

Claim Rejections

Paragraph 2 of the Final Office Action rejected claims 1-13 and 24-25 under 35 USC 103(a) as being unpatentable over US Pat. No. 5,474,558 to Neubardt ("Neubardt") in view of Calancie et al's article entitled "Stimulus-Evoked EMG Monitoring During Transpedicular Lumbosacral Spine Instrumentation" ("Calancie"). Applicants respectfully traverse this rejection as follows.

Claim 1, as currently amended, recites a method of determining structural integrity of a bone within the spine of a patient, where the bone has a first aspect and a second aspect, and the second aspect separated from the first aspect by a width and located adjacent to a spinal nerve. The method comprises the steps of: (a) applying an electrical stimulus to said first aspect of said bone; (b) electrically monitoring a muscle myotome associated with said spinal nerve; (c) *automatically determining an onset neuro-muscular response* to the application of said electrical stimulus to said first aspect of said bone *by automatically increasing said electrical stimulus until said onset neuro-muscular response is detected*; and (d) *communicating to a surgeon* operating on the patient's spine *an onset electrical stimulus level* which causes said onset neuro-muscular response. (Emphasis added).

While Neubardt and Calancie are certainly relevant to performing pedicle integrity assessments associated with pedicle screw placement, neither of these references appear to disclose or provide any teaching, much less motivation, for the claimed feature of "*automatically determining an onset neuro-muscular response* to the application of said electrical stimulus to said first aspect of said bone *by automatically increasing said electrical stimulus until said onset neuro-muscular response is detected*," nor the claimed feature of "*communicating to a surgeon* operating on the patient's spine *an onset electrical stimulus level* which causes said onset neuro-muscular response." These distinctions are important in the success of the Applicant's invention, which advantageously automates the process of pedicle integrity testing.

As explained in prior submissions, pedicle screw testing has traditionally been performed by specially trained neurophysiologists who apply (or direct the application of) an electrical stimulus to the instruments used to prepare the pedicle and/or introduce the pedicle screw. Significantly, these neurophysiologists also required to interpret the resulting EMG waveforms on the associated muscle myotomes and communicate their findings to the surgeon performing the spine surgery. This is disadvantageous in that the surgeon and patient are at the mercy of the schedule of the neurophysiologist, particularly for hospitals in remote areas or in hospitals that do not have neurophysiology teams on staff. It is also disadvantageous in terms of the added costs of having the neurophysiologist attend the case, particularly for hospitals in remote areas where the surgeon and/or hospital may get charged for the travel costs of the neurophysiologist (e.g. mileage, airfare, hotel accommodations, etc...) in addition to the professional service fees associated with the actual surgery. Both Neubardt and Calancie employ this traditional screw test scenario.

As expressly acknowledged in Paragraph 2 (page 2, line 23 to page 3, line 2) of the Final Office Action, Neubardt fails to disclose determining an onset neuro-muscular response to the application of the electrical stimulus to the first aspect of bone. Importantly, Neubardt is also silent regarding the *automatic* determination of onset neuro-muscular response, not to mention the claimed feature of doing so "*by automatically increasing said electrical stimulus until said onset neuro-muscular response is detected*" and the claimed feature of "*communicating to a surgeon* operating on the patient's spine *an onset electrical stimulus level* which causes said onset neuro-muscular response." Calancie does not cure these deficiencies.

Calancie describes a traditional screw test scenario, where "the electrophysiologist" (a.k.a., neurophysiologist) employs a traditional EMG system to guide a surgeon during the screw test procedure. In contradistinction to the claimed feature of "*automatically* determining an onset neuro-muscular response to the application of said electrical stimulus to said first aspect of said bone *by automatically increasing said electrical stimulus until said onset neuro-muscular response is detected*," in Calancie the neurophysiologist is the party determining the onset neuro-muscular response by **manually** increasing the electrical stimulus. For example, "*we* established the absolute threshold for evoking EMG during stimulation of the screw..." (Page 2782, Col. 1, lines 32-33), "*we* increased the intensity from zero only until an evoked EMG response was seen..." (Page. 2781, Col. 2, lines 13-15), and "because the technique does not use signal averaging the *decision-making process* is much more immediate..." (Page 2784, Col. 2, lines 25-26) (Emphasis added).

In the "Response to Arguments" section starting on Page 7 of the Final Office Action, it was asserted that the system of Calancie "receives EMG signals in response to a nerve

stimulation, and therefore automatically determines the muscle response after stimulation..." While Calancie does display the muscle response after stimulation, it does not appear to *automatically* determine the onset neuro-muscular response, nor do so by *automatically* increasing the electrical stimulus until the onset neuro-muscular response is detected. Instead, Calancie merely discloses displaying the resulting EMG waveforms from each stimulation. The present invention, on the other hand, determines the **onset** neuro-muscular response, which (by way of example only) may be defined as an EMG response meeting predetermined criteria (See, e.g., page 18, lines 13-15). Moreover, Calancie does not automatically determine the onset neuro-muscular response by *automatically* increasing the electrical stimulus until the onset neuron-muscular response is detected. Rather, as clear from page 2781, Col 2, lines 13-15 of Calancie, any increase in electrical stimulus occurs manually ("*we* increased the intensity from zero only until an evoked EMG response was seen...)."

Calancie similarly fails to cure the deficiency in Neurbardt regarding the claimed feature of "communicating to a surgeon operating on the patient's spine an *onset electrical stimulus **level*** which causes said onset neuro-muscular response." Indeed, based on the conventional EMG system used in Calancie, it merely communicates the *EMG waveform* to the user (see Fig. 2 on Page 2782), as opposed to the *onset electrical stimulus **level*** which causes the onset neuro-muscular response (as with the present invention). For example, "The *resultant EMG* from the muscles innervated by the nerve root alerts the surgical team to a potential perforation in the pedicle" (Page 2781, Col. 1, Text describing Fig. 1) and "*we* increased the intensity from zero only until an evoked *EMG response* was seen..." (Page 2784, Col. 2, lines 25-26) (Emphasis added).

The present invention, in contrast, does not communicate the actual EMG waveform to the user, but rather communicates the *onset electrical stimulus* ***level*** which causes the onset neuro-muscular response. In this fashion, interpretation by a neurophysiologist is not required. Instead, the surgeon performing the spine surgery (as opposed to a neurophysiologist) can assess whether the onset electrical stimulus level causing the onset neuro-muscular response falls with the well established ranges deemed to be safe, unsafe, or of intermediate concern by simply observing the onset electrical stimulus level. This advantageously overcomes the drawbacks of having neurophysiologists perform screw test procedures (set forth above).

With these cited references being silent regarding the above-identified features of claim 1, (along with the other references of in the record), Applicants respectfully submit that one of ordinary skill in the art would not have been led to the present invention (as now claimed) after consulting with the cited references. Applicants respectfully submit that these references, whether taken alone or in combination, fail to contain the requisite teaching or suggestion that would have led one of ordinary skill in the art to the present invention as set forth in amended claim 1. Claim 1 is believed to be in proper condition for allowance and an indication of such is hereby respectfully requested. Claims 2-13 and 24-25, being dependent upon and further limiting independent claim 1, should be allowable for the reasons set forth in support of the allowability of claim 1, as well as the additional limitations they contain.

Paragraph 3 of the Final Office Action rejected claims 14 and 26 under 35 USC 103(a) as being unpatentable over Neubardt and Calancie applied to claim 1, and further in view of US Pat. No. 6,334,068 to Hacker ("Hacker"). Applicants respectfully traverse this rejection as follows.

Claim 14 depends from claim 1 and (as currently amended) further defines the step of communicating to the surgeon as "visually displaying to said surgeon an intensity level representing said onset electrical stimulus level causing said onset neuro-muscular response for said spinal nerve." Claim 26 depends from claim 14 and specifies that "visually displaying involves the use of at least one of multi-color LEDs and an integrated display."

As set forth above, Neubardt and Calancie are both silent regarding the claim 1 features of "*automatically determining an onset neuro-muscular response* to the application of said electrical stimulus to said first aspect of said bone *by automatically increasing said electrical stimulus until said onset neuro-muscular response is detected*," as well as the claimed feature of "*communicating to a surgeon* operating on the patient's spine *an onset electrical stimulus level* which causes said onset neuro-muscular response." Hacker does not cure these defects.

On page 5, lines 3-7, of the Final Office Action, it was asserted that Hacker discloses an intraoperative neuoelectrophysiological monitor that communicates to a user by "visually indicating an intensity level of the electrical stimulus causing the onset neuromuscular response" and doing so via "an integrated display." However, a close review of Hacker reveals that the display 34 appears to merely display traditional EMG waveforms and *not* (as with the present invention) an intensity level representing the onset electrical stimulus level causing the onset neuro-muscular response. This is evident, among other areas, with reference to Figure 14 where the last block in the series states "CPU Display of EMG Waveforms Without Offset Channels 1-9."

With Neubard, Calancie and Hacker each being silent regarding the above-identified features of claim 14 (as well as claim 1, from which claim 14 depends), Applicants respectfully submit that one of ordinary skill in the art would not have been led to the present invention as set forth in Claim 14 after consulting with the cited references, whether taken alone or in combination. Claim 14 is believed to be in proper condition for allowance and an indication of such is hereby respectfully requested. Claim 26, being dependent upon and further limiting independent claim 14, should be allowable for the reasons set forth in support of the allowability of claim 14, as well as the additional limitations it contains.

Paragraph 4 of the Final Office Action rejected claims 15-17 under 35 USC 103(a) as being unpatentable over Neubardt, Calancie and Hacker as applied to claim 14, and further in view of NeuroVision SE Nerve Locator/Monitor ("NeuroVision SE"). Applicants respectfully traverse this rejection as follows.

Claim 15 depends from claim 14 and (as currently amended) further defines the step of visually displaying the intensity level representing the onset electrical stimulus level causing the onset neuromuscular response as comprising "illuminating lights." Claim 16 depends from claim 14 and (as currently amended) further defines the step of visually displaying the intensity level representing the onset electrical stimulus level causing the onset neuromuscular response as comprising "illuminating lights of varying colors." Claim 17 depends from claim 16 and further defines that "each color corresponds to a predetermined warning to the user."

As stated above, Neubard, Calancie and Hacker are each silent with regard to the claim 14 feature of "visually displaying to said surgeon an intensity level representing said

onset electrical stimulus level causing said onset neuro-muscular response for said spinal nerve," much less the claim 1 (from which claim 14 depends) features of "*automatically determining an onset neuro-muscular response* to the application of said electrical stimulus to said first aspect of said bone *by automatically increasing said electrical stimulus until said onset neuro-muscular response is detected*," or "*communicating to a surgeon* operating on the patient's spine *an onset electrical stimulus level* which causes said onset neuro-muscular response." The NeuroVision SE manual does not correct these defects.

More specifically, while the NeuroVision SE manual does appear to employ light emitting diodes (LED) of varying colors, these appear to merely communicate modes of operation (see, e.g. Chapter 6, last sentence on page 1 and chart on top of page 2), as opposed to the claim 14 feature of "visually displaying to said surgeon an intensity level representing said onset electrical stimulus level causing said onset neuro-muscular response for said spinal nerve" wherein visually displaying comprises "illuminating lights" (claim 15) or "illuminating lights of varying colors" (claim 16).

With Neubard, Calancie, Hacker and the NeuroVision SE manual each being silent regarding the above-identified features of claims 15 and 16 (as well as claim 14, from which claim 15 depends), Applicants respectfully submit that one of ordinary skill in the art would not have been led to the present invention as set forth in Claims 15 and 16 after consulting with the cited references, whether taken alone or in combination. Claims 15 and 16 are believed to be in proper condition for allowance and an indication of such is hereby respectfully requested. Claim 17, being dependent upon and further limiting independent claim 16, should be allowable for the reasons set forth in support of the allowability of claim 16, as well as the additional limitations it contains.

Paragraph 5 of the Final Office Action rejected claims 18-23 under 35 USC 103(a) as being unpatentable over Neubardt and Calancie applied to claim 1, and further in view of US Pat. No. 5,284,153 to Raymond ("Raymond"). Applicants respectfully traverse this rejection as follows.

Claim 18 depends from claim 1 and (as currently amended) adds the feature of "audibly indicating to said surgeon an intensity level representing said onset electrical stimulus level causing said onset neuro-muscular response for said spinal nerve."

The Office Action states that "Neubardt and Calancie...fail to disclose the use of an audible indicator for indicating an intensity level of the *response*" (Page 6, lines 11-13) (Emphasis added). Applicants again respectfully point out that claim 18 is ***not*** directed at the use of an audible indicator for indicating an intensity level of the EMG *response* (as asserted in the Final Office Action). Rather, claim 18 is directed at audibly indicating an intensity level of the onset electrical *stimulus* causing the onset neuro-muscular response. This is a significant distinction between the present invention and the prior art. This void is not cured by Raymond. Nor does Raymond cure the voids in Neubardt or Calancie regarding the claim 1 features of "*automatically determining an onset neuro-muscular response* to the application of said electrical stimulus to said first aspect of said bone *by automatically increasing said electrical stimulus until said onset neuro-muscular response is detected*," or "*communicating to a surgeon* operating on the patient's spine *an onset electrical stimulus level* which causes said onset neuro-muscular response."

With Neubard, Calancie and Raymond each being silent regarding the above-identified features of claim 18 (and claim 1, from which claim 18 depends), Applicants respectfully submit that one of ordinary skill in the art would not have been led to the present invention as set forth in Claim 18 after consulting with the cited references, whether taken alone or in combination. Claim 18 is believed to be in proper condition for allowance and an indication of such is hereby respectfully requested. Claims 19-23, being dependent upon and further limiting independent claim 18, should be allowable for the reasons set forth in support of the allowability of claim 18, as well as the additional limitations they contain.

CONCLUSION

Favorable consideration and allowance of the claims in this application is respectfully requested. In the event that there are any questions concerning this Amendment or the application in general, the Examiner is cordially invited to telephone the undersigned attorney so that prosecution may be expedited.

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